



# SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

## FORM 10-K

(Mark One)

☒ ANNUAL REPORT UNDER SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2000

☐ TRANSITION REPORT UNDER SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission File Number: 0-15324

## STAR SCIENTIFIC, INC.

(Exact name of registrant as specified in its charter)

Delaware  
(State of incorporation)

52-1402131  
(I.R.S. Employer Identification No.)

801 Liberty Way  
Chester, VA 23836  
(Address of principal executive offices)

(804) 530-0535  
(Registrant's telephone number,  
including area code)

### Securities registered pursuant to Section 12(g) of the Act:

Common Stock, \$.01 par value  
(Title of Class)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy of information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

The aggregate market value of the Registrant's voting stock held by non-affiliates of the Registrant as of March 1, 2001 is approximately \$25,595,850. Shares of voting stock held by each executive officer and director and by each person who owns 5% or more of the Registrant's voting stock have been excluded in that such persons may be deemed affiliates of the Registrant. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

Number of shares outstanding of each class of common equity as of March 1, 2001: 59,008,127 shares of Common Stock.

### DOCUMENTS INCORPORATED BY REFERENCE:

None

## NOTE ON FORWARD-LOOKING STATEMENTS

This report on Form 10-K contains certain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. The Company has tried, whenever possible, to identify these forward-looking statements using words such as anticipates, believes, estimates, expects, plans, intends and similar expressions. These statements reflect the Company's current beliefs and are based upon information currently available to it. Forward-looking statements involve known and unknown risks, uncertainties and other factors which could cause the Company's actual results, performance or achievements to differ materially from those expressed in, or implied by, such statements, and any such statements are qualified by reference to the following factors.

The Company is subject to risks, uncertainties and contingencies that include, without limitation, the risks of operating in the tobacco industry even as a health oriented tobacco technology company, the challenges inherent in new product development initiatives, including market acceptance of the Company's products and proposed new products, the Company's ability to raise the capital necessary to grow its business and unforeseen difficulties in the management of growth, potential disputes concerning the Company's intellectual property, competition from companies that may have certain competitive advantages over the Company, the Company's dependence on key employees and its relationship with Brown & Williamson Tobacco Corporation, a key strategic customer, supplier and lender, and the Company's decision not to join the Master Settlement Agreement (MSA). Other risks include further regulatory restrictions on the sale and marketing of tobacco products given the health concerns related to the use of tobacco products generally, the effect of state statutes adopted under the MSA and any subsequent modification of the MSA, litigation, including litigation related to the MSA, and the effects of excise tax increases on tobacco consumption rates.

See additional discussion under Factors That May Affect Future Results under Item 1 below, and other factors detailed from time to time in the Company's other filings with the Securities and Exchange Commission.

### 1 PART I

#### Item 1. Business

##### General

Star Scientific, Inc. (Star) and its wholly-owned subsidiary, Star Tobacco & Pharmaceuticals, Inc. (ST&P and together with Star, the Company) are engaged in: (1) the development of scientific technology for the curing of StarCured(TM) tobacco so as to prevent, retard or significantly reduce the formation of carcinogenic toxins present in tobacco and tobacco smoke, primarily, the tobacco specific nitrosamines (TSNAs); (2) the development of tobacco products that deliver substantially less carcinogenic toxins, namely TSNAs, along with enlarged health warnings and comparative content information so that adult tobacco consumers will have the option to make informed choices about the use of tobacco products which pose a range of serious health related risks (the TSNA levels in the Company's tobacco products will continue to be substantially reduced to very low levels, measured in parts per billion, using the StarCured(TM) tobacco curing process); (3) the manufacture and sale of four discount cigarette brands which currently contain only a small portion of its very low-TSNA StarCured(TM) tobacco (only because of Star's initial limited supply and its existing contractual delivery requirements of millions of pounds of very low-TSNA tobacco to Brown & Williamson Tobacco Corporation (B&W), the third largest tobacco company in the United States, as the Company remains committed to increase the percentage of very low-TSNA tobacco in its discount products as its supply of very low-TSNA tobacco increases during the next two growing seasons) and which are equipped with a carbon (charcoal)/acetate filter which reduces additional gas phase toxins; (4) the development of very low nitrosamine smokeless tobacco products, i.e., moist snuff and hard snuff tobacco, using the StarCured(TM) tobacco curing process to produce cured tobacco with very low levels of carcinogenic TSNAs; and (5) the research and continued development of smoking cessation products.

The Company's primary focus will continue to be the research and development of products that deliver less toxins. The Company's overall objective is to reduce the range of serious health hazards associated with the use of smoked tobacco products. Accordingly, its primary corporate mission is to demonstrate the commercial viability of products that deliver less toxins and are potentially less harmful, although the Company has attempted to share with adult consumers the fact that there is not now sufficient evidence to demonstrate that reduced toxin delivery can be quantified in terms of reduced health risk. The Company fully accepts the evidence showing links between smoking tobacco and a variety of diseases and premature death and believes that it is unlikely that the health risks of smoked tobacco can be completely eliminated. Nevertheless, in a world where an estimated 1.2 billion people smoke and use other tobacco products, there is an urgent need to reduce the toxicity of tobacco products to the maximum extent possible given available technologies. The Company believes that it has a corporate responsibility to continue to expand its research and development efforts to manufacture tobacco products in the least hazardous manner possible given available technology, particularly the StarCured(TM) tobacco curing process. The Company believes it has the technology to reduce carcinogenic TSNAs to the lowest possible levels and has demonstrated that the method it has developed for curing tobacco using the StarCured(TM) tobacco curing process can be scaled up to meet broad commercial needs in the United States and abroad. The Company is also committed to continuing to advocate meaningful federal regulation for all tobacco products and has publicly announced its support for

comprehensive regulation of tobacco products by the United States Food and Drug Administration (the FDA).

The Company has an exclusive, worldwide license under patents issued and patents pending relating to methods to prevent or substantially reduce the formation of TSNAs in tobacco including the StarCured(TM) tobacco curing process. TSNAs are generally regarded by recognized cancer researchers and respected scientists to be among the most abundant and potent carcinogens in tobacco and tobacco smoke.

The Company's revenues are generated principally through ST&P. ST&P's predecessor, a closely held private company, was organized in 1990 and, until 1994, primarily was engaged in the business of manufacturing cigars and cigarettes for others as a contract manufacturer. By late 1994, ST&P had commenced development and commercialization of its own brands of discount cigarettes using primarily Virginia flue-cured tobacco and

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competed principally on the basis of price. At about that same time, ST&P commenced a program of research and development relating to the development of a range of tobacco products that deliver less toxins as well as tobacco cessation products wherein ST&P secured certain Investigatory New Drug applications (INDs) from the FDA to commence human clinical testing. Shortly thereafter, ST&P shifted its near-term research to technology focused on reducing the carcinogenic TSNAs in the tobacco leaf and tobacco smoke. In February 1998, ST&P merged with Eye Technology, Inc., a publicly-held OTC Bulletin Board company based in Minneapolis, Minnesota. While Eye Technology technically was the surviving corporation, in effect control of the surviving corporation shifted to the former stockholders of ST&P and the management of ST&P became the control management of the survivor in the merger. By December 30, 1998, the assets and liabilities that comprised the pre-merger business of Eye Technology, Inc. had been sold or liquidated, and the stockholders of Eye Technology voted to change its name to Star Scientific, Inc. The Company's primary corporate focus from that time forward has centered on the development of reduced toxin, and potentially reduced risk, tobacco products, and, on a more long-term basis, development of smoking cessation products either with a joint venture partner or a corporate pharmaceutical partner with significant resources, and/or an experience in scientific and regulatory infrastructure so as to assist and accelerate the Food and Drug Administration's New Drug Application regulatory process necessary for market entry.

The StarCured(TM) tobacco curing process, to which the Company has an exclusive license, as discussed herein, from Regent Court Technologies (Regent Court), involves the use of specially designed curing barns and in certain applications microwave and/or electronic beam technology. The StarCured(TM) process virtually precludes and/or substantially reduces the formation in the tobacco leaf of the carcinogenic TSNAs, which are widely believed by medical and scientific experts to be among the most potent and powerful cancer-causing toxins present in tobacco and in side stream tobacco smoke. In 1999 and 2000, the Company processed over 3.5 million pounds and approximately 19 million pounds, respectively, of very low-TSNA flue-cured tobacco using the StarCured(TM) process, and believes that this process can be applicable to burley and other varieties of tobacco on a broad-scale commercial basis. Star continues to support research and technological development directed to varieties other than flue-cured tobacco and will conduct limited experiments this year in Kentucky on burley tobacco in conjunction with Associate Professor Harold Burton and his staff at the University of Kentucky's Department of Agronomy and The Burley Tobacco Growers Cooperative Association, Inc.

Star's long-term strategy is to encourage other tobacco manufacturers to utilize and sub-license the StarCured(TM) tobacco curing technology to produce very low-TSNA tobacco (carcinogenic NNKs and NNNs at 200 parts per billion and below). Further, Star is committed to continue to explore the development of products that deliver less toxins and are potentially less harmful than conventional smoked tobacco, namely smokeless tobacco products, as well as the development of tobacco cessation products. The Company has started the process of integrating its very low-TSNA StarCured(TM) tobacco into ST&P's present discount cigarette brands. ST&P presently markets four brands, namely, SPORT(R), MAINSTREET(R), VEGAS(R) and G-SMOKE(R), all of which have activated charcoal filters and contain approximately 3% of very low-TSNA flue-cured tobacco because of the limited supply of very low-TSNA tobacco at this time. The Company expects over the next two growing seasons to be able to significantly increase the amount of StarCured(TM) low-TSNA flue-cured tobacco in ST&P's four existing cigarette brands which utilize a carbon/acetate filter that reduces additional gas phase toxins. In October 2000 the Company launched its first very low-TSNA conventional premium cigarette, Advance(R), in two test markets: Richmond, Virginia and Lexington, Kentucky. Advance(R) also has a carbon/acetate filter aimed at reducing the levels of certain additional vapor phase toxins. Unlike conventional brands of cigarettes, Advance(R) has enhanced health warnings on the back of each pack as well as in a series of package onserts attached to each pack of Advance(R).

In February 2001, the Company and B&W signed a non-binding Letter of Understanding (Letter of Understanding). The transactions contemplated by the Letter of Understanding are subject to execution of definitive agreements. Under one of the provisions of the Letter of Understanding, B&W will undertake to test market the Advance(R) brand and potentially to market this brand on a national basis, if its market tests are successful. The Company intends to launch its own very low-TSNA cigarette brand by the 3rd quarter of 2001.

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Under the Letter of Understanding, it is anticipated that Star will process approximately 18-20 million pounds of very low-TSNA tobacco cured using the StarCured(TM) tobacco curing process per year for each of the next three years for sale to B&W and for its

own use. The production of this amount of StarCured(TM) tobacco will allow the Company to integrate its very low-TSNA StarCured(TM) tobacco into ST&P's four existing brands, to launch a new very low-TSNA flue-cured cigarette brand aimed at the generic market and very low-TSNA smokeless products. Contemporaneously it intends to fulfill its tobacco supply commitments to B&W. (See Relationship with B&W).

## **Products**

See Note 12 of the Company's Consolidated Financial Statements for financial information about the Company's segments.

### **Leaf Tobacco**

In 1999 and 2000, Star processed and sold over 3.5 million and approximately 19 million pounds, respectively, of very low-TSNA flue-cured tobacco that had been cured using the StarCured(TM) tobacco curing process. The vast majority of these sales were made to B&W, pursuant to Star's contractual arrangements with B&W described elsewhere in this Report. These sales accounted for approximately 10% and 21% of the Company's net sales in 1999 and 2000, respectively. Under the February 2001 Letter of Understanding, it is anticipated that the Company will process approximately 18-20 million pounds of very low-TSNA flue-cured tobacco in each of the next three growing seasons beginning in 2001, for sale to B&W and for use in the Company's own brands. The tobacco will be cured using the StarCured(TM) tobacco curing process.

The bulk of processed tobacco sales occur in the third and fourth quarter of each year, resulting in higher revenues in those quarters. The Company's long-term goal is to derive an increasingly larger percentage of its revenues from sublicensing the StarCured(TM) tobacco curing process to major cigarette manufacturers.

### **Discount Cigarettes**

ST&P manufactures and sells four brands of discount cigarettes through approximately 225 tobacco distributors throughout the United States. These cigarettes are sold as discount brands. ST&P does not engage in extensive advertising or marketing programs for its cigarette products, but relies primarily upon communications with distributors, product placement by its field sales force (the field sales force focuses primarily on placing ST&P's products with retailers in Texas, Florida, Mississippi and Minnesota), pricing appropriate for discount cigarettes, and, to a lesser extent, on brand, product appearance and taste in order to compete in the marketplace. Star has avoided any marketing efforts aimed at young persons, and the Company is committed to keeping its products out of the hands of youngsters. There were no export sales by the Company in 2000.

In an effort to implement the Company's corporate mission to develop products that deliver less toxins and potentially less harmful tobacco products (although the Company does not now have any evidence to support the scientific conclusions that such products can be classified or considered to be reduced risk products), the Company intends to phase its very low-TSNA tobacco which has been cured through the StarCured(TM) tobacco curing process into its discount cigarettes within the next two growing seasons. The Company is hopeful that meaningful future regulations by the FDA will provide appropriate scientific and regulatory guidelines and standards under which tobacco products can be classified as reduced risk products. As of July 1, 1999, ST&P changed all of its filters to activated carbon/acetate because several leading health advocates and respected research scientists believe that activated charcoal filters reduce certain vapor phase toxins in tobacco smoke. Since January 2001 the Company has undertaken to increase the amount of activated charcoal in its filters to 30 mg for all new production of ST&P's discount brands. The Company intends to continue to use activated charcoal filters in all of ST&P's discount cigarettes, and in Star's new low-TSNA flue-cured cigarette brand which the Company hopes to develop and market in 2001 for the generic cigarette market.

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### **Low-TSNA Cigarettes**

Star launched the first very low-TSNA cigarette, Advance(R), in October 2000 in 2 test markets--Richmond, Virginia and Lexington, Kentucky. Advance(R) is the first conventional cigarette to be manufactured to deliver less carcinogenic TSNA's. The Advance(R) cigarette reduces additional toxic smoke constituents through a unique dalmatian type activated carbon/acetate filter. Advance(R) is also different from conventional premium brands because it provides adult tobacco consumers with enhanced health warnings (not required by the Surgeon General) and comparative content information on the back of the package. Advance(R) also has informational package inserts that contain additional health and related information on the chemical constituents in Advance(R) compared to leading lights brands as well as detailed information about the range of adverse health consequences associated with long-term smoking that affords adult consumers the opportunity to make an informed choice about products which continue to expose the user to a range of health risks.

Star intends to introduce a new low-TSNA cigarette brand in 2001. The Company intends this brand to be a nationally available low-TSNA cigarette, though the Company plans on focusing sales in Texas, Florida, Minnesota and Mississippi where the Company's field sales force is positioned.

## Smokeless Tobacco Products Containing Very Low-TSNA Tobacco

Scientific research has shown that TSNA's may be the most significant carcinogens in smokeless tobacco products commonly known as chew, dip and snuff. Accordingly, during this past year, Star devoted substantial resources toward the development of very low-TSNA smokeless tobacco products and intends to introduce two of these products, a moist snuff and a hard tobacco product, in 2001. Star views these two new flagship smokeless products as significant innovations that will continue to transform the tobacco industry, just as its work with low-TSNA tobacco has created a new industry standard. However, despite continued research and development, no assurance can be given at this time that such products will be developed and successfully commercialized.

### Tobacco-Flavored Chewing Gum and Lozenges and Chewing Gum Containing Tobacco Extract

Approximately four years ago, the Company produced for pilot Phase I testing both a chewing gum and a tobacco lozenge, each containing very low-TSNA tobacco, as potential smoking cessation products. The gum/lozenge products contained nicotine, as well as the MAO-inhibitor known to be present in tobacco. In anticipation of a then pending legislative proposal to provide the FDA with new legislative authority to regulate tobacco products, the Company submitted and received approval of an IND for the gum product from the FDA. The Company commenced a Phase I Human Clinical Trial in the second quarter of 1998 in order to attempt to demonstrate the safety of this product for smoking cessation purposes. Given the present uncertain status of the FDA's authority to regulate tobacco products, among other factors, it now appears that to be sold as pharmaceutical products these tobacco-containing cessation products would be required to undergo all of the preclinical and clinical testing required of a new drug product. It seems unlikely at the present time that undertaking such testing would produce an adequate return on investment except if Star partners with an established pharmaceutical or healthcare company that has the necessary scientific infrastructure to adequately institute the types of clinical testing necessary to secure an NDA from the FDA. Star continues to investigate and explore opportunities for these products in Western and Eastern Europe, and in other countries where regulating authorities appear to be more receptive to the development of potentially reduced risk products that deliver less toxins. Star has taken a public position, unanimously supported by its Board of Directors, that it is in favor of comprehensive FDA regulation of all tobacco products. Star continues to explore entering into a joint venture, partnership and/or technology license, preferably with a major pharmaceutical company, to produce tobacco cessation products using StarCured(TM) tobacco as the focal point of such products.

### Sales and Marketing

ST&P's four brands of discount cigarettes are each sold in a variety of sizes and styles such as king size and 100s, soft pack and hinged box, regular flavor and menthol, and full flavor, lights and ultra lights. ST&P utilizes its own specified blend of tobaccos in each brand. The blend consists of Virginia flue-cured, burley and oriental varieties of tobacco, which is typical of American-style cigarettes.

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ST&P uses stylized packaging designs for its four brands of discount cigarettes. As is typical in the cigarette industry, ST&P utilizes different colors, such as green for menthol and similar designs on its packaging to denote different product styles. It is ST&P's strategy to rely to a large degree upon distributors to promote ST&P's brands to retail customers. ST&P provides to its distributor customers, for redistribution to retailers, point-of-sale materials such as posters, pole signs, display racks and counter top and floor displays. Also, ST&P produces marketing materials for use by distributors and their direct sales force to promote ST&P cigarettes to their retail customers.

ST&P sells its discount cigarettes through approximately 225 tobacco distributors throughout the United States. Of these 225 distributors, approximately 90 are located in Texas, Florida, Minnesota, and Mississippi where Star's sales force is now concentrated. The distributors maintain state and, where applicable, municipal government tobacco product licenses, apply state and/or local cigarette tax stamps when needed to resell the cigarettes. ST&P delivers its products directly to distributors mainly by common carrier trucks. ST&P's distributor customers primarily serve convenience stores, gas stations and other outlets and stores. No one distributor accounted for more than 10% of ST&P's revenue in 2000. The overall number of distributors was reduced from approximately 325 in 1999 to approximately 225 in 2000 due to price increases as well as the Company's focus on enhancing its market share in states in which it does not have purported obligations to make payments into escrow under state qualifying statutes enacted pursuant to the Tobacco Master Settlement Agreement (the Master Settlement Agreement or MSA).

Three of the Company's officers, Mr. Jonnie R. Williams, Star's Chief Executive Officer, Mr. David M. Dean, Star's Vice President of Sales and Marketing, and Mr. Sheldon Bogaz, ST&P's Vice President of Trade Operations, lead the Company's sales and marketing activities. Mr. Bogaz supervises a staff of seven regional sales representatives who direct ST&P's field sales force.

During 2000, ST&P re-positioned and consolidated its field sales force and reanalyzed its approach given the realities of competition from foreign and domestic companies selling discount brands. By the end of 2000, ST&P had 35 field sales personnel positioned in Texas, Florida, Minnesota and Mississippi. In 2001, ST&P will continue to expand its field sales force in those states.

During 2000, ST&P experienced substantial sales growth. ST&P believes that the price increases imposed upon the major cigarette

manufacturers, arising from the settlement of major litigation, created an increased demand for low-price cigarettes. In 2000, ST&P expanded its marketing and sales organization to respond to the anticipated increase in demand, not only for its present products, but also for ST&P's anticipated low-TSNA cigarettes and smokeless tobacco products.

The Company intends to test market and launch a new very low-TSNA flue-cured cigarette brand in the third quarter of 2001. This brand will be equipped with a carbon/acetate filter. This new low-TSNA brand, whose name will be announced shortly before the test marketing, will be distributed by the Company and will be aimed at the generic cigarette market. The Company anticipates that its very low-TSNA flue-cured brand will be available nationally but that sales will be initially focused in those states in which the Company maintains a sales force.

## **Purchasing**

Star purchases its very low-TSNA tobacco for its leaf tobacco sales from StarCured(TM) participating tobacco farmers who cure their tobacco in specifically designed StarCured(TM) barns. Star believes that it will be able to purchase a sufficient supply of flue-cured, StarCured(TM) leaf tobacco from these farmers for its own use and to satisfy commitments to B&W for the foreseeable future. The Company anticipates that it will be able to process the tobacco purchased from the farmers within its Chase City processing facility within one to three days of delivery to the facility.

During 2000, the majority of tobacco used in ST&P's cigarettes was purchased from B&W's Export Leaf Division in cut rag form, meaning that the tobacco has been cut, processed and flavored to ST&P's

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specifications, and is ready when delivered to ST&P for the manufacturing process. ST&P expects to continue purchasing cut rag, low-TSNA StarCured(TM) tobacco and other tobacco for the next several years from B&W's Export Leaf Division and thereafter to either continue purchasing cut rag tobacco from B&W Export Leaf Division or to purchase increasing amounts of tobacco needed for its business from other sources. Buying tobacco from B&W's Export Leaf Division allows ST&P to avoid having to dedicate substantial amounts of working capital to tobacco inventories.

At the end of 2000, Star had approximately 858,000 pounds of burley tobacco in inventory. Star continues its R&D to attempt to perfect the StarCured(TM) tobacco curing process for burley tobacco, and anticipates conducting additional tests with burley tobacco during the 2001 growing season in conjunction with the University of Kentucky's Department of Agronomy, The Burley Tobacco Growers Cooperative Association, Inc. and Star's scientific and technical advisors. Once the outcome of the on-going work on burley tobacco is known, Star will make a decision on how to proceed with its program for burley tobacco. While Star believes that the StarCured(TM) process is applicable to burley tobacco, no assurance can be given at this time that the low-TSNA StarCured(TM) tobacco curing process for burley tobacco will be developed and successfully commercialized during 2001.

## **Manufacturing**

All of the flue-cured tobacco which the Company plans to use in 2001 and thereafter in the production of its very low-TSNA tobacco either for sale to B&W and potentially other parties, or for gradual incorporation into ST&P's own cigarettes, or in Star's smokeless tobacco products, will be cured using the StarCured(TM) tobacco curing process. The StarCured(TM) tobacco curing process utilizes specially equipped curing barns and in certain applications microwave and/or electronic beam technology. The specially designed curing barns, which incorporate the StarCured(TM) tobacco processing technology, are manufactured exclusively for Star by Powell Manufacturing Company of Bennettsville, South Carolina (Powell). These specially designed barns are erected on site at the tobacco farms which provide Star with its source of very low-TSNA tobacco. A total of 1,125 Star barns have been manufactured, and approximately 880 have been delivered to farmers who produce flue-cured tobacco. It is anticipated that 136 flue-cured barns will be shipped prior to the 2001 growing season to farmers requesting additional barns. In 2000, 100 barns were delivered to farmers in Kentucky in connection with the research, development and testing of the StarCured(TM) tobacco curing process for burley tobacco in conjunction with the previously-mentioned joint program with The Burley Tobacco Growers Cooperative Association, Inc. Star will conduct limited experiments this year in Kentucky. Although Star believes that the StarCured(TM) tobacco curing process is equally applicable to both flue-cured and burley tobacco, Star acknowledges that this pilot program may well take a longer period of time to perfect than the flue-cured program.

Star does not anticipate purchasing any additional barns from Powell in 2001 because the Company has sufficient barns in place to process approximately 18 to 20 million pounds of StarCured(TM) flue-cured tobacco which will meet the Company's needs for this growing season. Financing for approximately half of these barns has been provided by B&W (see Relationship With B&W). Upon completion of the continuing experimental program for burley tobacco, additional barns may be required for the StarCured(TM) processing of burley tobacco.

In early 2000, Star's processing facility in Chase City underwent a substantial expansion of its capacity to process significantly larger amounts of very low-TSNA tobacco, as well as provide sufficient space for the installation of new equipment to be used in conjunction with the manufacturing of both of Star's anticipated flagship smokeless tobacco products. This expansion allowed Star to



process approximately 19 million pounds of StarCured(TM) tobacco during 2000. As a result of the expansion, the Chase City facility will have more than adequate capacity for volumes anticipated for B&W under the Letter of Understanding, as well as Star's need for tobacco, and for additional needs should those needs arise.

ST&P expanded its cigarette manufacturing capability in 2000 by outsourcing a portion of its manufacturing through a contract with B&W to manufacture cigarettes. Through this outsourcing, the Company hopes to avoid

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the need to buy new cigarette manufacturing equipment. The tobacco used in manufacturing ST&P's cigarettes is combined with filters and paper in a maker which produces finished cigarettes, which, in turn, are placed in a packer which provides packaging into standard 20-cigarette packs and ten- pack cartons. ST&P believes its manufacturing facilities, plus the additional contract manufacturing relationship now in place with B&W, will allow ST&P to respond to its growing demand for the foreseeable future.

#### Relationship with B&W

On October 12, 1999, the Company and B&W entered into a Supply Agreement under which B&W agreed to purchase StarCured(TM) tobacco. During 1999 and 2000, Star produced and delivered to B&W approximately 3.5 million pounds and 19 million pounds, respectively, of very low-TSNA StarCured(TM) processed tobacco. Some of this tobacco has been or will be purchased by the Company for use in ST&P's own discount cigarettes, Star's very low-TSNA cigarettes, and in Star's new hard tobacco and moist snuff products.

In addition during 2000, B&W collaborated with the Company in the development of a new very low-TSNA cigarette named Advance(R). B&W also has been manufacturing cigarettes for ST&P, supplying leaf tobacco to ST&P for use in its tobacco products, and warehousing burley tobacco for Star.

The non-binding Letter of Understanding envisions a new set of agreements which would supercede the Supply Agreement. Under the Letter of Understanding, B&W intends to expand its commitment to purchase very low-TSNA StarCured(TM) tobacco during each of the next three years through Star's established StarCured(TM) tobacco program. The Letter of Understanding also addresses a range of other issues, including B&W test marketing of the Advance(R) brand, and the future production of a potentially less-hazardous, low-TSNA hard tobacco product that is intended to be aesthetically pleasing to both present cigarette smokers and current users of smokeless tobacco products. The transactions contemplated by the Letter of Understanding are subject to execution of definitive agreements and the approval of Star and B&W's respective Boards of Directors. The Company also expects that the agreements, consistent with the Letter of Understanding, will extend B&W's long-term credit facility, which has been used to support Star's expanded barn program and the continuing development of innovative tobacco products focused on reduced toxin delivery.

#### Competition

The Company's primary competition for cigarettes is from the four majors, that is, Philip Morris, the brands of which accounted for more than 50% of all cigarette sales in the United States in 2000, R.J. Reynolds, B&W and Lorillard, as well as Vector (the parent company of Liggett), each of which has substantially greater financial and operating resources than the Company. The Company also encounters significant competition from several other smaller U.S. manufacturers of cigarettes, as well as importers of cigarettes manufactured in foreign countries. Many of these manufacturers and importers have substantially greater financial, manufacturing, marketing and other resources than the Company. Further, several newer discount competitors have not, and it appears do not intend to make deposits into escrow accounts purportedly required by the MSA, allowing these competitors to undercut the current discount market and unfairly compete against ST&P for discount cigarette sales.

ST&P's current discount cigarettes compete principally on the basis of price and possibly quality of product. Generally speaking, there are three price categories of cigarettes in the United States, premium, which includes such brands as Marlboro(R) and Camel(R), full-price, which includes such brands as Doral(R) and GPC(R), and discount, which as a group account for only a small percentage of the U.S. cigarette market. Each of ST&P's brands is priced in the discount category. Other competitive factors include package design, taste and the amount of marketing support provided to distributors and retailers. At the consumer level, brand loyalty also is a significant factor.

In 2000, the Company established an escrow account as required by the MSA for sales of cigarettes in 1999, and in 2000 it has focused sales (and its field sales force) to increase its market share in states that were not part

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of the MSA in order to minimize its MSA escrow payment obligation. However, in the 46 states that did join the MSA, ST&P faces significant competition from cigarette manufacturers and captive distributors of overseas manufacturers who have not made MSA escrow payments. Such companies are able to sell discount cigarettes at a substantial cost reduction compared to ST&P and as a result ST&P is at a significant cost disadvantage in competing with these entities.



The Company is not aware of any other company which currently produces very low-TSNA tobacco on a commercially viable basis. The Company believes that no producer of discount cigarettes appears to be incorporating a very low TSNA tobacco and activated carbon/acetate filters into their discount brands. There have been published reports that at least one of the major cigarette manufacturers is developing its own low-TSNA cigarettes, which may or may not be brought to market during 2001. One Swedish company, Swedish Match, has worked with various varieties of tobacco under crop management environments and other methods in an effort to maintain low-TSNA levels in its smokeless products. Star is not aware of any other company that now incorporates very low-TSNA tobacco into its cigarettes or other smoked tobacco products. B&W now has in its possession very low-TSNA tobacco from both the 1999 and 2000 growing season, but has not yet made a public announcement of when it will start using that tobacco in its current products or in a new product. However, recent announcements by several of the major tobacco companies indicate that certain of these companies either have commenced or intend to explore the production of low-TSNA tobacco and the incorporation of low-TSNA tobacco into their cigarettes. Also, the industry has initiated a program that is intended to require all tobacco sold at auction to be cured in a manner that is intended to result in reduced levels of TSNAs. Star believes that if it is successful in commercializing its unique very low-TSNA cigarettes and/or in developing and commercializing very low-TSNA smokeless tobacco products, it is inevitable that many of the major tobacco companies will follow its lead and may seek to sub-license the StarCured(TM) technology.

If the Company is successful in developing and commercializing smoking reduction or cessation products, it will encounter stiff competition. Smoking cessation products that are approved for sale in the United States by the FDA are primarily nicotine delivery products (nicotine only) designed to wean the patient from nicotine addiction over a period of time ranging from 30 days to six weeks. These products are referred to as nicotine replacement products. Three products, Nicorette(R), a nicotine chewing gum, and Nicotrol(R) and NicoDerm(R), both transdermal nicotine patches, constituted substantially all of the U.S. pharmaceutical nicotine market in 1999 and 2000. All of these products are sold over-the-counter. Zyban(R), (bupropion), a prescription drug which originally was developed and is still sold under another proprietary name as an antidepressant, was introduced to the market in 1997 and has been demonstrated to be useful as a cessation product. Star understands that sales of Zyban(R) to date have been substantial and that Zyban(R) is often prescribed by physicians to be used in conjunction with nicotine delivery products.

Star's principal competitors in the cessation and reduction market would include Smith Kline Beecham, the McNeil Consumer Division of Johnson & Johnson, Glaxo-Wellcome and Pharmacia-Upjohn, all of which have capital resources, research and development staffs, facilities, experience in conducting clinical trials and obtaining regulatory approvals, and experience in manufacturing and marketing their products which are significantly greater than those of Star. In addition, there are several companies developing new technologies aimed at smoking cessation therapies. There also are a number of consumer products which do not require FDA approval as therapeutic drug products but which nevertheless are advertised as alternatives to smoking or as a help in the reduction of smoking. For example, at least one of the leading United States confectionery chewing gum manufacturers has advertised its gum products as an alternative to cigarettes. There are also non-tobacco cigarettes produced with fillers such as lettuce and herbs. In addition to the use of consumable products for smoking cessation or reduction purposes, medical practitioners and others have developed a variety of programs intended to assist a person in withdrawing from nicotine dependence. Treatments used include psychological counseling, hypnosis, group therapy and behavior modification techniques. There can be no assurance that Star can overcome regulatory barriers to marketing its tobacco-containing cessation products or that Star's competitors will not succeed in developing technologies and products that are more effective than Star's product candidates, that are less toxic than Star's products or that would render Star's products obsolete or non-competitive.

## **Government Regulation**

The manufacture and sale of cigarettes and other tobacco products and of pharmaceutical products are subject to extensive federal and state governmental regulation in the United States and by comparable authorities in many foreign countries. These national agencies and other federal, state and local entities regulate, among other things, research and development activities and the testing, manufacture, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion of Star's products.

There are multiple bills pending before the 107th Congress and in several state legislatures which, if enacted, would significantly change the United States tobacco industry. Some of these federal bills contain provisions which would provide substantial federal government funds for smoking cessation programs and products, as well as incentives to tobacco companies and others to produce less toxic or reduced-risk tobacco products under potential specific standards. Star is unable to predict what effect, if any, these provisions, if enacted, would have on Star's technology for very low-TSNA tobacco or the sale of Star's smoking cessation products and/or potentially reduced-risk tobacco products. The Company believes, however, that any bill that requires manufacturers to reduce or disclose levels of TSNAs in tobacco or tobacco smoke would be beneficial.

Star announced on February 29, 2000, at a press conference held at the Dirksen Senate Office Building in Washington, D.C., its support of a bi-partisan tobacco labeling Bill (S. 2125) introduced by Senators Frank Lautenberg (D. N.J.), Richard Lugar (R. IND.), Richard J. Durbin, (D. ILL.), and Lincoln D. Chafee (R. R.I.). To the best of Star's knowledge, it was the only tobacco company asked to support this bi-partisan bill which focused upon brand disclosures not now mandated by the Surgeon General or HHS. The Senate Bill, entitled the Smoker's Right to Know and Truth in Tobacco Labeling Act, would have significantly enhanced the current tobacco

package warning labels and required disclosure of toxic ingredients and health effects. The Bill would have required all manufacturers to disclose cancer-causing agents, including carcinogenic TSNA's, as well as the percentage of such carcinogens relative to the average of such concentration of such carcinogen in the sales weighted average of all cigarettes marketed in the United States.

In March 2000, Representatives Greg Ganske (R, Iowa), John Dingell (D, Michigan), and Henry Waxman (D, California) co-sponsored the introduction of the FDA Tobacco Authority Amendments Act. This bill would have given the FDA regulatory power over all tobacco products. The Company actively supported this Bill, and wrote a letter to the sponsors asking them to consider an amendment which would require manufacturers to follow standards adopted by the FDA before making reduced risk claims. On March 9, 2001, the Company wrote to Representative Ganske to support the re-introduction of the FDA Tobacco Authority Amendments Act which took place on March 15, 2001.

In May 2000, Senators McCain (R, Arizona) and Dr. William Frist (R, Tennessee) introduced Senate Bill (S. 2566) entitled The National Youth Smoking Reduction Act. The central goal of the legislation was to reduce the number of youths who are smoking and to provide the FDA with regulatory authority over tobacco products. Senator McCain echoed the views of the Company when he commented that a significant aspect of the proposed Bill would include language that provides a mechanism for lower-risk tobacco products to be tested, reviewed and approved. Senator Frist introduced a similar bill in January 2001. It is expected that Senator McCain will introduce an FDA tobacco bill during April 2001.

#### **President's Commission On Improving Economic Opportunity In Communities Dependent Upon Tobacco Production**

Star has been actively supporting the vast majority of the recommendations of The President's Commission on Improving Economic Opportunity in Communities Dependent upon Tobacco Production while Protecting Public Health. Star is keenly interested in supporting the American tobacco farming community and assisting farmers in obtaining higher prices for very low-TSNA tobacco, while promoting public health related issues by giving the farmers an opportunity to produce very low-TSNA tobacco using StarCured(TM) tobacco curing barns that have been provided to the farmers by Star. Star testified before the President's Commission in Louisville, Kentucky last year, and provided written comments on the Commissions' preliminary recommendations in March 2001.

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#### **FDA Regulation**

In 1996 the FDA promulgated regulations governing the sale and advertising of tobacco products designed primarily to discourage the sale to, and consumption by, adolescents and children. The authority of the FDA to promulgate such regulations was challenged in the federal courts by the major tobacco companies. A federal District Court upheld the FDA's authority to promulgate such regulations but ruled that certain of the regulations restricting advertising were invalid as violative of the constitutional right of free speech. On appeal, the United States Court of Appeals for the Fourth Circuit affirmed portions of the District Court opinion that held the FDA could not regulate tobacco advertising and ruled that the executive branch of the United States government, in particular the FDA, does not have any authority to regulate tobacco products generally. The federal government appealed the Appeals Court's ruling and the matter was heard by the United States Supreme Court in late 1999. On March 21, 2000, the Supreme Court in a five to four decision held that Congress has not given the FDA authority to regulate tobacco products as customarily marketed. Given the decision by the Supreme Court it is unclear whether Congress will act to grant such authority to the FDA, although legislation that would create such authority has been introduced.

The Company believes that in the future reasoned FDA regulation should better enable the Company to compete in its particular market niche. The Company has publicly stated its position in favor of reasoned FDA regulation of tobacco products for approximately the last three years. The Company has shared the results of the StarCured(TM) tobacco curing technology with the FDA. (See Research and Development-Prior Development of CigRx(TM) for a discussion of the Company's prior submission of a cigarette product to the FDA.) The Company believes that the commercial value of the StarCured(TM) curing process will depend in part upon its validation by the scientific, health care and public health communities and on the basis of the type of standards likely to be mandated by Congress and the FDA, should jurisdiction be congressionally granted to the FDA.

#### **Institute of Medicine**

On February 22, 2001, the Institute of Medicine issued a comprehensive report, entitled Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction, in response to a request from the FDA to assess the scientific basis for possible harm reduction relating to the use of tobacco. This voluminous report suggests, among other findings, that it is scientifically feasible to design and manufacture a range of emerging potential reduced-exposure products (which the report referred to as PREPs), but that without appropriate governmental regulation and independent scientific evaluation of PREPs, the public is left without clear information regarding the degree to which these products have reduced the risks associated with smoking. The Company provided testimony before the Institute of Medicine and shared certain of its scientific and applied research and findings related to the development of products which deliver less of certain toxins (TSNA's) and other gas and vapor phase toxic substance in tobacco smoke. Star's innovative products that deliver less toxins and the StarCured(TM) process were referred to in the Institute of Medicine's discussion of PREPs.

## **Federal Trade Commission**

The requirements for health warnings on cigarettes is governed by the Federal Cigarette Labeling and Advertising Act (Labeling Act). The Labeling Act imposes labeling and advertising requirements on the manufacturers, packagers and importers of cigarettes and requires any company wishing to sell cigarettes within the United States to submit a plan to the Federal Trade Commission explaining how it will comply with the warning label display requirements. Star has submitted labeling plans for its cigarette products in the past, and the Federal Trade Commission (the FTC) has approved such plans. Similar requirements relating to smokeless tobacco products are included in the Comprehensive Smokeless Tobacco Health Education Act of 1986. Also, Star shared with the FTC its enhanced warning labels for Advance(R) prior to the initiation of the test marketing of Advance(R) in October and submitted a labeling plan for Advance(R) that was subsequently approved by the FTC. Star's warning labels and comparative content disclosure of toxic smoke constituents were subsequently utilized in the Advance(R) test marketing program. Star intends to provide the FTC with similar information prior to the introduction of its new very low-TSNA cigarettes and smokeless tobacco products.

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## **Bureau of Alcohol, Tobacco and Firearms**

Manufacturers and importers of tobacco products are taxed pursuant to regulations promulgated by the federal Bureau of Alcohol, Tobacco and Firearms under authority of the Internal Revenue Code of 1986, as amended. The Company's tobacco products are subject to tax under such regulations.

## **State and Municipal Laws**

The sale of tobacco products is subject to taxation through excise taxes in all fifty states. State excise taxes range from \$.025 per pack in Virginia to \$1.11 per pack in New York. The federal excise tax on cigarettes rose from \$.24 per pack in 1999 to \$.34 in 2000, and will increase to \$.39 per pack in 2002. In addition, some states permit municipalities to impose an additional sales tax, and many municipalities do so. The state and municipal sales taxes are imposed upon wholesalers and/or retailers but not manufacturers, and therefore the Company has no liability for such taxes. The Company is required by many states, however, to report its shipments of cigarettes to distributors/retailers located within their jurisdiction. Star is aware of at least two states, Massachusetts and Minnesota, which have recently adopted laws and regulations regarding the disclosure by manufacturers of certain chemical constituents in their products. If upheld Star intends to fully comply with such laws and believes it will benefit from such disclosure.

## **Master Tobacco Settlement Agreement**

In November 1998, 46 states and several U.S. territories entered into a settlement agreement (the Master Settlement Agreement or MSA) to resolve litigation that had been instituted against the major tobacco manufacturers. The Company was not named as a defendant in any of the litigation matters and chose not to become a participating manufacturer under the terms of the Master Settlement Agreement. As a nonparticipating manufacturer, the Company is required to satisfy certain purported escrow obligations under statutes which the Master Settlement Agreement required participating states to pass, if they were to receive the full benefits of the settlement. The so-called level playing field statutes require nonparticipating manufacturers to fund escrow accounts that could be used to satisfy judgments or settlements in lawsuits that may at some future date be filed by the participating states against such nonparticipating tobacco manufacturers. Under these statutes the Company is obligated to place an amount equal to \$1.88 per carton for 1999 and \$2.09 in 2000, and increased amounts per carton for subsequent years (\$2.72 in 2001- 2002, \$3.35 in 2003-2006 and \$3.77 thereafter), in escrow accounts for sales of cigarettes occurring in the prior year in each such state after the effective date of each state specific statute. An inflation adjustment is also added to these deposits at the higher of 3% or the Consumer Price Index each year. Such escrowed funds will be available to satisfy tobacco-related judgments or settlements, if any, in some states. If not used to satisfy judgments or settlements, the funds will be returned to the Company 25 years after the applicable date of deposit on a rolling basis. Also, absent a challenge to the state specific statutes or some accommodation as to the escrow amounts, the failure to place the required amounts in escrow could result in penalties to the Company and potential restrictions on its ability to sell tobacco products within particular states. Because all of the MSA states have passed the so-called level playing field statutes, the Company expects that a material portion of its cigarette sales will continue to be subject to such purported escrow obligations.

As of January 1, 2000, thirty-eight states and the District of Columbia had adopted so-called model level playing field statutes and Star's purported net obligations under those statutes was approximately \$11.6 million with respect to 1999 sales. As of January 1, 2001, forty-six states had adopted model level playing field statutes. Star's purported net obligations under those statutes is approximately \$13.0 million with respect to 2000 sales. The Company's Board of Directors is anticipated to authorize the Company to fund the escrow obligation for 2000 on or before April 15, 2001, again under protest. The funds placed in escrow continue to be an asset of the Company and the Company will receive the interest income generated by the escrow deposits.

After almost two years of negotiations with the National Association of Attorneys General (NAAG), the Company concluded that NAAG had little interest in working with Star to come to a reasonable solution under which the Company could become a participant in the Master Settlement Agreement. Accordingly, on